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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/330,629 06/11/99 STEWART

C JG-RP-4796

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NEW YORK NY 10152

HM12/1010

EXAMINER

HILL, S

ART UNIT

PAPER NUMBER

1617

DATE MAILED:

10/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/330,629

Applicant(s)

STEWART, CLAUDIA CHERNEY

Examiner

San-ming Hui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) 15-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment and remarks on page 3, line 1 – page 4, line 2 in the amendment submitted July 13, 2001 have been considered and found persuasive to remove the rejections under 35 USC 112, 2nd paragraph set forth in the previous office action mailed March 13, 2001.

Claims 15-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dori (WO93/11140) in view of Cooper et al. (US Patent 4,242,359), references of record in the office action mailed March 13, 2001.

Dori teaches the method of treating viral infection and decreasing viral titer broadly by topically administering the metallo-organic cobalt compounds, including compound No. 96 in the instant specification, with a concentration of 0.5 to 10mg/ml (0.05 to 1% by wt) (See page 13, line 16-19; page 19-27, experiment 1-7; claims 1 and 11). Dori also teaches the dosage form of the metallo-organic cobalt compounds may be ointments, salves, and creams (See page 12, lines 16-17).

Dori does not expressly teach the method of prophylaxis for Human Immunodeficiency Virus (HIV) infection by topically administering the metallo-organic cobalt compound No. 96 in the instant specification to the site on the subject which is exposed to the HIV. Dori also does not expressly teach the method of using a condom as an applicator to topically apply the compound No.96.

Cooper et al. teaches a method of topical administration of a medical agent by applicators including a condom is known in the art (See abstract and col. 8, line 40-44).

Therefore it would have been obvious for one of ordinary skill in the art at the time the invention was made to topically administer the instant compounds to the site on the subject by using a condom as an applicator for the prophylaxis of HIV infection.

One of ordinary skill in the art would have been motivated to utilize the instant compounds for the prophylaxis of HIV infection because the compounds of Dori are known to be effective in treating viral infections and decreasing viral titer, broadly. It is therefore reasonable to expect the very same compounds, including compound 96, to be useful in prophylaxis, or reduction in the incidence of, any viral infections including those caused by HIV strains.

Furthermore, one of ordinary skill in the art would have been motivated to topically administer the instant compound by using a condom as an applicator because the method of topical administration of pharmaceutical actives by applicators including a condom is known in the art.

Response to Remarks

Applicant's remarks submitted July 13, 2001, regarding Dori failing to teach that a method for treating viral infection could also be useful in prophylaxis of viral infection and therefore failing to teach that the elected compound, Compound 96, is effective for prophylaxis of HIV infection have been considered but not found persuasive because Dori teaches that Compound 96 can actually reduce the viral titer. See page 19-27, experiment 1-7 herein. Therefore one of ordinary skill in the art would have reasonably expected Compound 96 to be useful in lowering the incidence of viral infection in any group of subjects (i.e. prophylaxing against HIV infection).

Applicant's assertion that "one skilled in this art would understand that once a virus has entered a cell or infected a patient, the virus itself is changed" and that Dori's method of treating viral infection is only effective against the changed form of the virus has been considered but not found persuasive as to the non-obviousness of employing the instant compound for prophylactic use against HIV because Compound 96 is known to effectively lower the intracellular viral titer and therefore, would be expected to lower the incidence of viral infection (i.e. to prophylax against HIV infection) as recited in the instant claims.

Applicant's remarks regarding "obvious to try" in regard to the teachings of Dori have been considered but not found persuasive because the cited prior art is seen to render the claimed method of prophylaxis obvious as discussed above.

In regard to the data in Charts No. 1 and 2 and applicant's remarks regarding the same in the amendment submitted July 13, 2001 relates to HSV infection have been considered but not found persuasive because the data presented is not seen to be

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relevant to the recited method of prophylaxis against HIV infection in the instant claims.

It is applicant's burden to demonstrate, as by affidavit or declaration, any unexpected results for the claimed invention over the prior art. Further, it is applicant's burden to explain how any such data presented demonstrates an unexpected result for the claimed invention over the closest prior art. See MPEP 716.02, also 716.02 (a) - (g). Furthermore, the unexpected results should be demonstrated with evidence that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance. *Ex parte Gelles*, 22 USPQ2d 1318, 1319 (Bd. Pat. App. & Inter. 1992). Moreover, evidence as to any unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). In the instant case, it is not seen how the data in the charts presented (not in affidavit or declaration) relating to HSV infection show an unexpected result for the elected method relating to HIV infection.

Applicant's further assertion that a compound which is used for treatment of disease simply does not have the same effect as a prophylactic measure and one skilled in this art would have no reason to expect such properties merely from the fact that a compound is known as a treatment agent have been considered but not found persuasive because Compound 96, the preferred compound herein is a known antiviral agent which has been demonstrated in the prior art to lower the viral titer. One of ordinary skill in the art would therefore clearly expect this effect of lowering viral titer to lower the incidence of viral infection (i.e. to prophylax for HIV infection).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (703) 305-1002. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

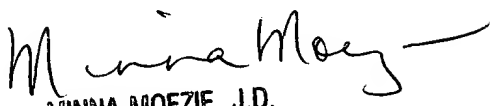
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

San-ming Hui
October 8, 2001


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600